K101543

510(k) SUMMARY

AUG 3 0 2011

1. **Date prepared**
   August 28, 2011

2. **Sponsor information**
   Tyson Bioresearch, Inc.
   5 F., # 22, Ke E. Road iii., science based industrial park
   Chun-Nan, Miao-Li county, Taiwan 350

   Correspondent:
   WEN-HAI TSAI
   Phone: 886-37-585988
   Facsimile: 886-37-585996

3. **Device name and classification**
   Device Name:
   TysonBio AC100 Blood Glucose Monitoring System
   TysonBio AC100 Pro Blood Glucose Monitoring System
   TysonBio AC200 Blood Glucose Monitoring System
   TysonBio AC200 Pro Blood Glucose Monitoring System

   Common Names:
   Blood Glucose Monitoring System

   Classification:
   Classification: Class II
   Classification Regulation: 21 CFR 862.1345
   Product Code: CGA (Glucose Oxidase, Glucose)
   NBW (System, Test, Blood Glucose, Over The Counter)
   Panel - Clinical Chemistry and Toxicology

4. **Device description**

   The TysonBio AC100/AC100 Pro Blood Glucose Monitoring System and the TysonBio AC200/AC200 Pro Blood Glucose Monitoring System is an amperometric biosensor, It is adopted for its ease of use, its ability to process accurate results utilizing only a small volume of blood, and its quick response time. The TysonBio AC100/AC100 Pro Blood Glucose Monitoring System and the TysonBio AC200/AC200 Pro Blood Glucose Monitoring System consist of three main products: the meter, Test Strips and Control Solutions. Use only

TysonBio AC100/AC100 Pro Test Strips for TysonBio AC100/AC100 Pro Blood Glucose Monitoring Systems, TysonBio AC200/AC200 Pro Test Strips for TysonBio AC200/AC200 Pro Blood Glucose Monitoring Systems, and use TysonBio AC100/AC100 Pro Control Solutions for TysonBio AC100/AC100 Pro Blood Glucose Monitoring Systems, TysonBio AC200/AC200 Pro Control Solutions for TysonBio AC200/AC200 Pro Blood Glucose Monitoring Systems to perform quality checks.

5. **Intended use**

TysonBio AC100 Blood Glucose Monitoring System:

The TysonBio AC100 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The TysonBio AC100 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The TysonBio AC100 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The TysonBio AC100 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly). The TysonBio AC100 contains a voice function but this function is not intended for users with impaired vision.

The TysonBio AC100 Test Strips are for use with the TysonBio AC100 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

TysonBio AC100 Pro Blood Glucose Monitoring System:

The TysonBio AC100 Pro Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, or forearm. The TysonBio AC100 Pro Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use lancing devices.

The TysonBio AC100 Pro Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not

changing rapidly). The TysonBio AC100 Pro contains a voice function but this function is not intended for users with impaired vision.

The TysonBio AC100 Pro Blood Glucose Test Strips are for use with the TysonBio AC100 Pro Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

TysonBio AC200 Blood Glucose Monitoring System:

The TysonBio AC200 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The TysonBio AC200 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The TysonBio AC200 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The TysonBio AC200 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The TysonBio AC200 Test Strips are for use with the TysonBio AC200 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

TysonBio AC200 Pro Blood Glucose Monitoring System:

The TysonBio AC200 Pro Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, or forearm. The TysonBio AC200 Pro Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use lancing devices.

The TysonBio AC200 Pro Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The TysonBio AC200 Pro Blood Glucose Test Strips are for use with the TysonBio AC200 Pro Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

6. **Test principle**

   The test principle is based on electrochemical biosensor technology using glucose oxidase. There has been no change to the fundamental scientific technology.

7. **Predicate device**

   Easy Step Blood Glucose Monitoring System (K090629)

   Comparison to predicate device

   The modifications to the device encompass:

   - Addition of selectable voice guidance on/off function (for TysonBio AC100 model only)
   - Addition of hypoglycemic and hypoglycemic alarm setting
   - Removal of backlight
   - Extension of meter memory capacities
   - Changes in outer case appearance
   - Change to auto coding.

   There have been no changes to the operating principle, intended use or functionality.

8. **Performance characteristic summary**

   Evaluations of the TysonBio AC100 / A100 Pro Blood Glucose Monitoring System and the TysonBio AC200 / AC200 Pro Blood Glucose Monitoring System were studied in the laboratory and in a clinical setting using persons with diabetes. The results were compared to results from the currently marketed Easy Step Blood Glucose Monitoring System and to a laboratory method. The studies showed substantially equivalent performance with the current Easy Step Blood Glucose Monitoring System.

9. **Conclusion**

   The TysonBio AC100 / AC200 Blood Glucose Monitoring System is substantially equivalent to the predicate Easy Step Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Building 66
Silver Spring, MD 20993

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Chun-Nan, Miao-Li County
China (Taiwan) 350

AUG 3 0 2011

Re: k101543
Trade/Device Name: TysonBio AC100/AC100Pro/AC200/AC200Pro Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: July 21, 2011
Received: August 25, 2011

Dear Mr. Tsai

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K101543

Device Name: TysonBio AC100 Pro Blood Glucose Monitoring System

Indication for Use:

The TysonBio AC100 Pro Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, or forearm. The TysonBio AC100 Pro Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use lancing devices.

The TysonBio AC100 Pro Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly). The TysonBio AC100 Pro contains a voice function but this function is not intended for users with impaired vision.

The TysonBio AC100 Pro Blood Glucose Test Strips are for use with the TysonBio AC100 Pro Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Prescription Use X	And/Or Over the Counter Use X
(21 CFR Part 801 Subpart D)	(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101543

Indication for Use

510(k) Number (if known): K101543

Device Name: TysonBio AC100 Blood Glucose Monitoring System

Indication for Use:

The TysonBio AC100 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The TysonBio AC100 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The TysonBio AC100 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The TysonBio AC100 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly). The TysonBio AC100 contains a voice function but this function is not intended for users with impaired vision.

The TysonBio AC100 Test Strips are for use with the TysonBio AC100 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Prescription Use _____ And/Or Over the Counter Use X
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101543

Indication for Use

510(k) Number (if known): K101543

Device Name: TysonBio AC200 Pro Blood Glucose Monitoring System

Indication for Use:

The TysonBio AC200 Pro Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, or forearm. The TysonBio AC200 Pro Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use lancing devices.

The TysonBio AC200 Pro Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The TysonBio AC200 Pro Blood Glucose Test Strips are for use with the TysonBio AC200 Pro Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Prescription Use ___X___ (21 CFR Part 801 Subpart D)

And/Or Over the Counter Use ___X___ (21 CFR Part 801 Subpart C)

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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101543

Indication for Use

510(k) Number (if known): K101543

Device Name: TysonBio AC200 Blood Glucose Monitoring System

Indication for Use:

The TysonBio AC200 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The TysonBio AC200 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The TysonBio AC200 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The TysonBio AC200 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The TysonBio AC200 Test Strips are for use with the TysonBio AC200 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Prescription Use _____ And/Or Over the Counter Use X
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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